

CARE ONE HEADACHE RELIEF ADDED STRENGTH- acetaminophen, aspirin and caffeine tablet, film coated
American Sales Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

American Sales Company Headache Relief Drug Facts

Active ingredient (in each tablet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- sinusitis
- arthritis
- a cold
- toothache
- premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 tablets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach

bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

When using this product

the recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if you are allergic to aspirin
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- diabetes
- gout
- arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - redness or swelling is present
 - any new symptoms occur
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or a loss of hearing occurs

These could be signs of a serious condition

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months

of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not use more than directed (see Liver warning)
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 tablets every 6 hours; do not exceed 8 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

store at 20°-25°C (68°-77°F)

Inactive ingredients

carnauba wax, crospovidone, FD&C blue no. 1 lake, hypromellose, microcrystalline cellulose**, povidone, propylene glycol, saccharin sodium, starch, stearic acid, titanium dioxide **may contain this ingredient

Questions or comments? 1-800-719-9260

Principal Display Panel

Compare to the Active Ingredients in Excedrin®

HEADACHE RELIEF

ADDED STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever/Pain Reliever Aid

See New Warnings Information



Headache Relief Carton Image 1

Drug Facts

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| | |
|------------------------------|-------------------|
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| Aspirin 250 mg (NSAID)*..... | Pain reliever |
| Caffeine 65 mg..... | Pain reliever aid |

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Drug Facts (continued)

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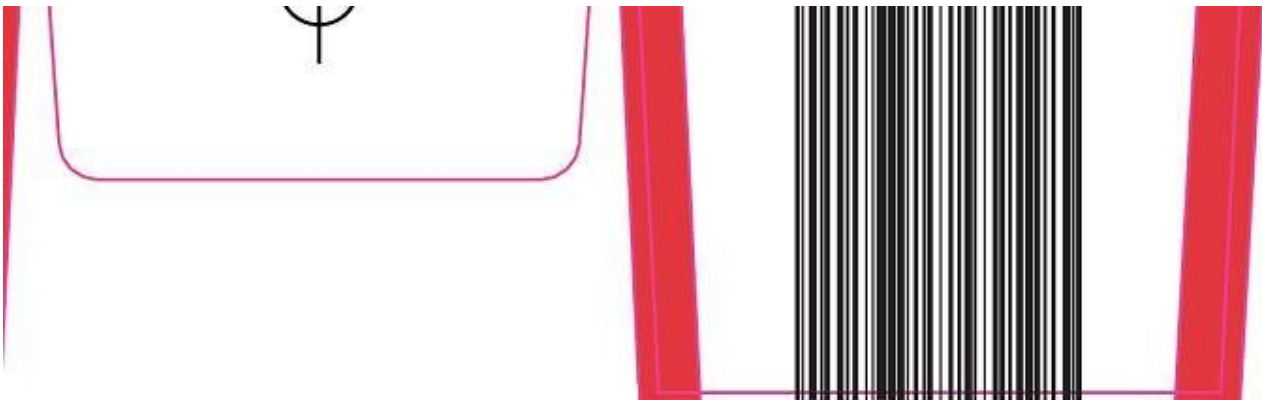
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Headache Relief Carton Image 2

CARE ONE HEADACHE RELIEF ADDED STRENGTH

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41520-430 |
| Route of Administration | ORAL | DEA Schedule | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 250 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 65 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSPOLYMER (UNII: 68401960MK) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYVINYL PIPERIDINE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | | Imprint Code | L430 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:41520-430-78 | 1 in 1 CARTON | | |
| 1 | | 100 in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343 | 04/13/2004 | |

Labeler - American Sales Company (809183973)

Revised: 6/2009

American Sales Company